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ATTORNEYS FOR DEFENDANTS-

New York University School of Medicine and New York University Hospitals Center

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as guardians ad litem of the infant, ROSIE GROSSBAUM,

Plaintiffs,

V.

GENESIS GENETICS INSTITUTE, LLC of the State of Michigan, MARK R. HUGHES, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of New York, ABC CORPS. 1-10, and JOHN DOES 1-10,

Defendants.

Hon. Garrett E. Brown, Jr.

Civil Action No. 07-1359 (GEB)

STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF THE MOTION OF DEFENDANTS NEW YORK UNIVERSITY SCHOOL OF MEDICINE AND NEW YORK UNIVERSITY HOSPITALS CENTER FOR SUMMARY JUDGMENT AND FOR FINALITY OF JUDGMENT

STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF THE MOTION OF DEFENDANTS NEW YORK UNIVERSITY SCHOOL OF MEDICINE AND NEW YORK UNIVERSITY HOSPITALS CENTER FOR SUMMARY JUDGMENT AND FOR FINALITY OF JUDGMENT

1. Plaintiffs Chaya and Menachem Grossbaum, individually and as guardians *ad litem* of their minor daughter Rosie, commenced this civil negligence action against Genesis Genetics Institute, LLC ("Genesis"), its founder and director Mark R. Hughes ("Dr. Hughes")

(collectively "Genesis" or "Dr. Hughes"), and the NYU defendants to recover damages in connection with the birth and raising of Rosie as a child affected by cystic fibrosis ("CF). (Exhibit A, Complaint.)

- 2. Because plaintiffs knew that they were both unaffected genetic CF carriers and faced an inherent 25% chance of giving birth to a CF-affected child, plaintiffs sought the advice and counsel of rabbis in their religious sect on what options they had regarding their desire to have a child. (Exhibit B, Deposition of Chaya Grossbaum, p. 15-19, 30-31, 37-47, 49-50, 64-66; Exhibit C, Deposition of Chaya Grossbaum, p. 11-13, 14-15, 20.)
- 3. The suggested course was to pursue a process of *in vitro* fertilization ("IVF") and preimplantation genetic diagnosis ("PGD"), and the recommendation was to see the NYU defendants' Frederick Licciardi, M.D. at the NYU IVF Center. (Exhibit B, p. 49-50, 64-65; Exhibit C, p. 12, 15, 20.)
- 4. The IVF aspects of the process were performed by Dr. Liciardi's group. The PGD aspects of the process were performed by Genesis and Dr. Hughes.
- 5. The initial IVF steps involved: obtaining blood samples from the plaintiffs and sending those samples to Genetics for the development of PGD test protocols specific to the plaintiffs' respective CF genes; inducing the development of, and obtaining several eggs from Mrs. Grossbaum; fertilizing the eggs with sperm from Mr. Grossbaum; developing embryos from the fertilized eggs over the course of two to three days; extracting a single cell from each of 10 PGD test-candidate embryos; sending the appropriately identified and packaged cells to Dr. Hughes at Genesis for PGD testing and analysis to determine the genetic suitability of the embryos for implantation to induce a pregnancy, along with controls and 10 media blanks for testing and analysis as a precaution against contamination of the cells' DNA; and, appropriately

storing the candidate embryos for further development, pending receipt of a report on the PGD test results from Dr. Hughes.

- 6. The PGD steps conducted by Genesis and Dr. Hughes involved: the testing of the plaintiffs' blood samples to determine which CF genes they carried; developing and conducting appropriate PGD tests designed to detect the presence or the absence of the genes in the embryonic cells sent by NYU, and to determine whether or not the cells' DNA had become contaminated; and submitting a written report to NYU regarding the test results and genetic evaluation or "call" for each of the cells, and regarding the tests results of the controls and blanks.
- 7. Based upon the PGD evaluation report's calls regarding the cells' respective genetic suitability; based upon the report's indication of success with the controls and blanks; and based upon the report's indication that there was no evidence of DNA contamination, the IVF process resumed with a medical evaluation of the growth of the candidate embryos that had remained to determine their embryological viability for implantation to induce a pregnancy; a consultation with the plaintiffs concerning the results of the genetic PGD tests and of the embryological evaluation of the two best-suited embryos; a decision by the plaintiffs to proceed with the implantation of the embryos; the implantation of the embryos; and monitoring the resulting pregnancy for several weeks.
- 8. Plaintiffs do not claim any failure on the part of Dr. Licciardi and the NYU defendants regarding the information provided about, or the performance of, the IVF procedures involved in this case other than with the interpretation of Dr. Hughes' report regarding the genetic suitability of the cell from embryo #7 and the selection of that embryo in lieu of embryo #10, which had not developed enough embryologically to be viable for implantation.

- 9. The focus of plaintiffs' case with respect to Genesis and Dr. Hughes is on their method of PGD testing and genetic analysis without the use of "markers" to enhance detection of the genetic testing phenomenon known as allele drop-out ("ADO"); on the allegedly understated risk information that Dr. Hughes conveyed to plaintiffs about the chances of his PGD tests causing them to have a CF-infected child; and on the accuracy of the PGD report, which allegedly conveyed misdiagnosed information to Dr. Licciardi.
- 10. In connection with the plaintiffs' decision to proceed with the IVF/PGD process, Dr. Licciardi and his staff informed the plaintiffs about all pertinent details of the IVF aspects of the process, and some aspects of the PGD process, specifically deferring to Dr. Hughes to provide the complete details of, and to answer all of the questions that the plaintiffs might have, about PGD. (Exhibit B, p. 56-61, 84-88; Exhibit C, p. 21-25.)
- 11. Dr. Licciardi recognized that his specialty was in the practice of IVF and that Dr. Hughes was the PGD specialist. (Exhibit D, Deposition of Frederick Licciardi, M.D., p. 9, 61, 63-64.)
- 12. Plaintiffs understood and accepted this division of specialties and expertise between Dr. Lucciardi and Dr. Hughes. (Exhibit B, p. 59-60.)
- 13. Dr. Hughes recognized that IVF practitioners such as Dr. Licciardi were experts in their field, but not experts in genetics and PGD as he was. (Exhibit E, 2/19/09 Deposition of Mark Hughes, M.D., Ph.D., p. 21-22; Exhibit F, 5/14/10 Deposition of Mark Hughes, M.D., Ph.D., p. 28, 30.)
- 14. Because of that recognition, Dr. Hughes undertook to go into pertinent details about the various aspects of PGD with the plaintiffs, what procedures PGD involved, and the risk

of a PGD misdiagnosis leading to the implantation and development of a CF-affected embryo and the resultant birth of a CF-affected child. (Exhibit E, p. 21-22.)

- 15. From Dr. Licciardi and from Dr. Hughes, plaintiffs understood, before they began the IVF/PGD process, that PGD was not 100% accurate, and that there was a risk of PGD misdiagnosis that could lead to the implantation of an CF-affected embryo and the resultant birth of a CF-affected child. (Exhibit B, p. 59-60, 69-72, 107-108, 111, 112, 114, 122 171-173, 175, 177; Exhibit C, p. 29, 34, 65.)
- 16. Although there is some dispute as to whether or not plaintiffs, contrary to their indications on consent forms, expressed to the defendants an intention not to undergo the post-conception prenatal tests recommended to them by the defendants and expressly agreed to on the forms, and as to whether Genesis and Dr. Hughes would or could have refused to perform the PGD testing had that intention been known, those disputes are completely immaterial to the resolution of plaintiffs' claims against the NYU defendants on this motion for summary judgment.
- 17. Plaintiffs understood from the information provided by the NYU personnel that the risk of a PGD misdiagnosis was as high as 10% with the success rate "above 90%," but they understood from their previous discussion with Dr. Hughes that he was very positive about the chances of success for the plaintiffs; that <u>his</u> success rate was much higher, 97%-98%; and that <u>his</u> risk rate was much lower and "minimal," 2% to 3%. (Exhibit B, p. 69-72, 111-112, 118-122, 141-142, 213-214; Exhibit C, p. 29, 31, 36-39, 48, 69-70.)
- 18. Dr. Hughes confirmed that he tells the patients that the risk rate with his testing is less than 2% or 1-2%, compared to a 3-5% risk rate with other PGD testing facilities. (Exhibit E, p. 30-31; Exhibit F, p. 41, 43.)

- 19. Plaintiffs decided to go forward with the IVF/PGD process based upon their discussion with Dr. Hughes and his assurance that the success rate would be 97-98%, with a risk rate of 2-3%. (Exhibit B, p. 69-72, 82, 120-122, 141-142, 213-214; Exhibit C, p. 31-32, 36-39, 48, 69-70.)
- 20. If Mrs. Grossbaum had been told that the success rate was less than 97-98% and the risk higher than 2-3%, but still far better than the inherent 25% risk she probably would not have had the embryos implanted. (Exhibit B, p. 213-214 ["If I was told that there was a chance, a greater chance than what we had originally understood, I would probably not have implanted the embryo."].)
- 21. Mr. Grossbaum was guided by and followed his wife's decisions regarding the process. (Exhibit C, p. 36-39.)
- 22. Neither plaintiff knew for sure what his or her decision would have been if they had been told that the success rate was not 97-98%, but closer to 90%. (Exhibit B, p. 217-218; Exhibit C, p. 69-70.)
- 23. On July 19, 2004, Dr. Hughes faxed his one-page PGD analytical report for use by Dr. Licciardi in determining which of the embryos were genetically suitable for implantation. (Exhibit G, 1-page "Morgenstern-Grossbaum results 07/19/2004"; Exhibit D, p. 40-41, 43, 45-46; Exhibit F, p. 62, 69-70.) Dr. Hughes expected that Dr. Licciardi would use and rely upon the information conveyed in the one-page report. (Exhibit F, p. 62, 69-70.)
- 24. Although two other communications from Genesis to NYU exist in the Genesis chart for the plaintiffs, a more formal analytical report and a note, there is no evidence of record that either of those communications were sent to, or received by, NYU. To the contrary, the

evidence of record demonstrates that neither of those documents were part of the NYU records. (Exhibit D, p. 44-45, 66; Exhibit H, Deposition of James Grifo, M.D., p. 31-32.)

- 25. Dr. Hughes' PGD analytical report stated generally that "All controls and media blanks worked as expected. These data are very clear. All media blanks showed no evidence of exogenous DNA contamination." (Exhibit G.)
- 26. Dr. Hughes' PGD analytical report mentioned allele drop-out ("ADO") only with respect to the cell from embryo #2, stating in the report's "call", or genetic suitability evaluation, that that cell was "Possibly affected ADO paternal," and noting, "For sample 2, since only the mutant maternal allele was observed, it is possible that the paternal allele also dropped out of CF 10, and could be affected." (Exhibit G.)
- 27. With respect to the cells from embryos 3 and 14, the PGD report's call stated, "No molecular signal." (Exhibit G.)
- 28. The PGD report noted that the cells from embryos 8 and 10 were carriers of the maternal CF gene, but that those embryos were genetically suitable for transfer, the call for each of those cells stating, "Carrier maternal -OK for transfer." (Exhibit G.)
- 29. With respect to the cells from the remaining embryos, 4, 7, 13, and 15, Dr. Hughes' PGD report's call was "Carrier at worst." (Exhibit G.)
- 30. Plaintiff's expert, Dr. Charles Strom, a geneticist with Quest Diagnostics, confirmed that the PGD report from Dr. Hughes indicated to Dr. Licciardi that the "Carrier at worst" embryos, including embryo 7 that is at issue in this case, were genetically suitable for implantation, as was embryo 8, the other embryo at issue in this case. (Exhibit I, Deposition of Charles Strom, p. 124.)

- 31. Dr. Licciardi understood that Dr. Hughes' PGD report meant that the "Carrier at worst" embryos, including embryo 7, were genetically suitable for implantation, as were the two "Carrier maternal -OK for transfer" embryos, 8 and 10. (Exhibit D, p. 52-56.)
- 32. The "Carrier at worst" embryos, including #7, were genetically suitable, because they would not produce a CF-affected child, since only one parental gene was affected and CF required both parental genes to be affected. (Exhibit D., 51-56; Exhibit J, Deposition of Dr. Samuel Pang, p. 69-75.)
- 33. The "Carrier at worst" embryos were genetically similar to the plaintiffs, each of whom was a CF "carrier," but neither of whom was affected with CF. (Exhibit B, p. 155, Exhibit H, p. 42; Exhibit J, p. 70.)
- 34. In addition to reviewing the PGD report from Dr. Hughes concerning the genetic suitability of the tested embryos, Dr. Licciardi morphologically evaluated the embryos to determine how well the embryos were growing, also on July 19, 2004. (Exhibit D, p. 53-54.)
- 35. Although embryo 10 was genetically evaluated on Dr. Hughes' report as "Carrier maternal -OK for transfer," it had not grown well enough in the Embryology Laboratory to be sufficiently viable for implantation; instead, embryos 7 and 8 were selected as candidates for implantation, because they were both genetically suitable simply carriers -- according to Dr. Hughes' PGD analysis, and they were biologically viable due to the quality of their growth and development. (Exhibit D, p. 51-56.)
- 36. Had Dr. Hughes advised Dr. Licciardi that ADO was a concern with embryos 7 and 8, as Dr. Hughes' report had indicated with respect to embryo 2, Dr. Licciardi would have followed Dr. Hughes' ADO concern and discussed that concern with the plaintiffs, because Dr. Hughes was the expert on ADO. (Exhibit D, p. 61, 63-64.)

- After reviewing the PGD report from Dr. Hughes, and evaluating the growth of the embryos, Dr. Licciardi discussed the embryo transfer with plaintiffs on July 19, 2004, informing them that the analysis involved both the genetic component from Dr. Hughes' PGD testing and the biological growth component from Dr. Licciardi's evaluation, and that the embryos were carriers at worst and genetically suitable for transfer, according to Dr. Hughes' report. (Exhibit B, 154-156; Exhibit C, p. 58-61; Exhibit D, p. 52-54, 62-63.)
- 38. Plaintiffs understood that Dr. Hughes's genetic evaluation indicated that the embryos were CF carriers, but not CF-affected, just like the plaintiffs themselves were CF carriers but not affected, and they consented to the implantation of the embryos 7 and 8, which was done that day. (Exhibit B, 154-156; Exhibit C, p. 58-61.) As Mrs. Grossbaum explained,
 - Q According to the records, it was July 19th, which would have been five days after the egg retrieval. Does that sound right?
 - A Yes.
 - Q. Tell me what happened.
 - A They told us to come for the implantation. They said some of the embryos that he tested that were good embryos had cystic fibrosis, and there were some good ones that did not have cystic fibrosis but they were carriers for CF. Did we want to use them? We said yes, and they implanted me with two I believe, two embryos, and they said both of them were carriers for CF.
 - Q Who had the discussion that you related to us?
 - A Dr. Liccardi.
 - Q. Was anyone else present for that discussion other than Dr. Liccardi and you? Was your husband there?
 - A Yes, I believe he was.
 - Q. Anybody else present?
 - A I don't remember.
 - Q. And when Dr. Liccardi said that there were some good embryos that were CF carriers and asked whether you wanted to go ahead with those, did you have an understanding of what a CF carrier was?
 - A Yes. I'm a CF carrier. It just means that you carry the gene for CF.

- Q. So in other words, it was your understanding that Rosie could be a CF carrier such as you or your husband?
 - A Correct.
- Q And was there any further discussion about that issue, other than what you just relayed to me now? Did you have any questions?
- A I don't think I had any specific questions. I knew what it meant to be a CF carrier.
- Q. So it was your understanding that according to the testing that Dr. Hughes' lab had done, that the two embryos that they were going to implant in you were both CF carriers?
- A Yes, and I said as long as it's just a carrier for CF, then that's fine for me. I don't care if she's a carrier for the gene. Everybody is a carrier for something.
 - Q. Anything else to that discussion that you haven't told us?
- A I mean, I think he just spoke specifically about what he was going to do, what the procedure was, how long it would take, but that's it. That's pretty much it.
 - Q Was the implantation done that day?
 - A Yes.

(Exhibit B, p. 154-156.)

39. The only evidence of record regarding whether the plaintiffs' daughter developed from embryo 7 or embryo 8 is the testimony of both Drs. Grifo and Pang that the medical probability is that it was embryo 8, because it was the more morphologically advanced of the two embryos in growth. (Exhibit H, p. 44-45; Exhibit J, p. 103-104, 114-116, 119-120.) Although plaintiffs' expert, Dr. Strom did not believe that there was a way to answer the question, the question was posed to him with respect to embryos 8 and 10, the latter not having been implanted. (Exhibit I, p. 127-128.) Plaintiff's other liability expert, Dr. Garry Cutting,

expressed no opinion on the subject. (Exhibit K, 9/29/09 report of Dr. Garry Cutting; Exhibit L, Deposition of Garry Cutting, M.D.)

- 40. Plaintiffs' liability expert, Dr. Strom, will not be testifying regarding the standard of care of the NYU defendants' Dr. Licciardi. (Exhibit I, p. 5.)
- 41. Dr. Strom testified that, according to Dr. Hughes' PGD report, the "Carrier at worst" embryos, <u>including embryo 7</u>, were genetically suitable for implantation, as was embryo 8, one of the two "Carrier maternal -OK for transfer" embryos. (Exhibit I, p. 124.)
- 42. Although there is a dispute between plaintiffs' additional liability expert, Dr. Cutting, and all of the other experts in this case, including Drs. Hughes, Strom, Pang, and Kangpu Xu, as to whether or not embryo 7 or embryo 8 posed the greater risk of genetic misdiagnosis and consequent CF development due to undetected ADO, that dispute is not material -- or contrary -- to the granting of summary judgment in favor of the NYU defendants, because no risk of ADO posed by those embryos was expressed in Dr. Hughes' PGD evaluation report to Dr. Licciardi.
- 43. In contrast with Dr. Licciardi, who is board-certified in obstetrics and gynecology as well as in reproductive endocrinology, and who has long maintained an active practice in IVF, Dr. Cutting is primarily a <u>pediatrician</u> and a <u>geneticist</u> who has not practiced as an IVF specialist. (Exhibit M, Curriculum Vitae of Dr. Licciardi; Exhibit N, Curriculum Vitae of Dr. Cutting.)
- 44. Dr. Cutting does not have the qualifications under New Jersey law to testify against Dr. Licciardi in this case.
- 45. Dr. Cutting's approach to this case also stands in contrast to both the geneticist, Dr. Hughes, who recognizes that IVF practioners do not, and are not expected to, understand genetics any more than he understands IVF, and to the IVF practioner Dr. Licciardi, who

recognizes the distinct areas of knowledge and expertise between himself and a geneticist such as Dr. Hughes. (Exhibit D, p. 61, 63-64; Exhibit E, p. 21-22; Exhibit F, p. 28.)

- 46. Instead of evaluating Dr. Licciardi's performance as an IVF practitioner, Dr. Cutting criticizes Dr. Licciardi as if Dr. Licciardi were a geneticist intimately familiar with the specialized techniques, language, and protocols of PGD testing.
- 47. Dr. Cutting's criticism of Dr. Licciardi also lacks substantial factual support, and the facts of record refute most of that criticism.
- 48. Dr. Cutting is a board-certified pediatrician and geneticist. (Exhibit N.) He viewed his purpose in this case as "offering an expert opinion on diagnostic procedures in PGD." (Exhibit L, p. 253, emphasis added) In Dr. Cutting's opinion, "[t]he appropriately done [PGD] analysis in 2004 when this was done should have been done with genetic markers." (*Id.*, p. 256.) Dr. Cutting has done only two PGD analyses, both using markers. (*Id.*, p. 117-118, 284, 285.) In Dr. Cutting's view, plaintiffs' daughter became affected with CF, because Genesis and Dr. Hughes did not use markers in their PGD testing, thereby failing to detect an ADO in one of the implanted embryos and misdiagnosing the genetic suitability of the embryo for implantation by Dr. Lucciardi. (*Id.*, p. 183, 186, 188-189, 192-193, 199.)
- 49. Dr. Cutting counsels, diagnoses, and tests patients on genetics as a geneticist. (Exhibit N, p. 13-23, 28.) Unlike Dr. Licciardi and his IVF colleagues at the NYU defendants, Dr. Cutting has not extracted eggs from patients, and he has not implanted embryos into patients. (*Id.*, p. 13-14.) As Dr. Cutting admitted in his deposition, IVF is <u>not</u> part of his program; "IVF, invitro fertilization is a program of obstetrics and gynecology. It is not under the institute of genetic medicine. **Invitro is not a part of the genetics program here. Just like surgery is not under genetics."** (*Id.*, p. 19, emphasis added.)

- 50. Dr. Cutting also admitted that he did not know the grading scale or the basis on which the NYU IVF team determined that one of the embryos in this case was not morphologically viable for implantation or transfer, and he further admitted that he could <u>not</u> talk about how the embryos were tracked in the NYU IVF lab, because "I'm not an embryologist. Not my area of expertise." (*Id.*, p. 65-67, emphasis added.) Dr. Cutting recognized that those functions were under the IVF specialty umbrella and areas of expertise for embryologists, "OB/GYN, maternal/fetal medicine, [and] reproductive endocrinology." (*Id.*)
- 51. Dr. Cutting additionally admitted that he was not an expert in IVF clinics and laboratories: "I can't say, I'm not expert in IVF laboratories. So, I've I've already indicated I'm not will talk about DNA labs but not I could cite to the areas where I have expertise and be more careful." (Exhibit L, p. 104, emphasis added.)
- 52. With respect to the current professional activities listed on his C.V. and those in which he was engaged in 2003-2005, Dr. Cutting explained that 10% of his time is devoted to his role as Director of the Post-Doctoral Training Programs in Medical Genetics, including, until 2008, his role as Director of Genetics Residency Programs; 15% of his time is spent as Director of the DNA Diagnosite Laboratory; his role as Professor of Pediatric Medicine is "primarily [his] research that would take about 70 percent" of his time; and the remaining 5% is devoted to time off. Exhibit L, p. 23-26.)
- 53. Dr. Cutting has been involved as an expert in 10 cases, <u>all involving PGD</u> as opposed to IVF; he has given 5 depositions including the two-stage deposition that he gave in this case; but he has never testified at trial. (Exhibit L, p. 35-40.)

- 54. Dr. Cutting's September 29, 2009 expert report criticized Dr. Licciardi regarding the decision to substitute embryo 7 in place of embryo 10. (Exhibit K., p. 1.) Specifically, Dr. Cutting opined that Dr. Licciardi:
 -failed to offer a reasonable level of care....in the counseling of the Grossbaums regarding alternatives for embryo transfer after it was discovered that the embryos recommended for transfer by Genesis Genetics were not suitable for transfer. Allele dropout (aka ADO) is a well established source of error in preimplantation genetic diagnosis. From the deposition of Dr. Licciardi, it was apparent that he was not aware of this potential cause for error. Dr. Licciardi indicated during his deposition that he did not understand the results of the genetic testing results transmitted by Genesis Genetics. There is also no documentation of what was said during the counseling session between Dr. Licciardi and the Grossbaum's [sic] regarding the risks of potential sources of error. Thus, Dr. Licciardi failed to adequately appraise the Grossbaums of the potential risks of using alternative embryos for transfer.

(Exhibit K, p. 1.)

- 55. Contrary to his report, Dr. Cutting acknowledged at his deposition that Dr. Licciardi was, in fact, familiar with the ADO mechanism. (Exhibit L, p. 69-70.) In particular, Dr. Cutting recited what Dr. Licciardi said in his deposition about Dr. Hughes' "call" or evaluation for embryo 2, that it was "Possibly affected due to "ADO paternal," signifying allele drop-out, which meant "[w]hen the test is performed and you don't get your answer, the feeling is you were able to test for one of the alleles." (Exhibit D, p. 50-51; Exhibit L, p. 69-70.)
- 56. Dr. Cutting also acknowledged that the "call" section of Dr. Hughes' report provided Dr. Licciardi with Dr. Hughes' genetic evaluation of the embryo; that "carrier at worst" meant that "the worst this could be is a carrier," a meaning which was "obvious"; and that the only mention of ADO and "possibly affected" was with respect to embryo 2. (Exhibit L, p. 70, 76-77, 218-219, emphasis added.)

- 57. As an IVF specialist, and admittedly <u>not</u> as a specialist in genetics or in PGD testing, Dr. Licciardi acknowledged at his deposition that he did not know what some of the geneticist abbreviations on Dr. Hughes' report meant, such as "T only," "G," or "G/T." (Exhibit D, p. 49-50.) However, there is nothing in Dr. Cutting's report or in his deposition testimony to establish that the standard of PGD knowledge for an IFV doctor was the same standard of knowledge as for a geneticist, or that the standard of care for an IVF practitioner encompassed the specialized terminology used by genetics specialists.
- 58. Contrary to Dr. Cutting's report, but confirmed by Dr. Cutting's deposition testimony, the record shows that Dr. Licciardi did understand that Dr. Hughes' "call" provided his "assessment of that embryo that was tested"; the significance of ADO; that ADO was indicated only for embryo 2; that "carrier at worst" meant "that one gene has been determined to be a cystic fibrosis gene and one has not, or it means that there was one gene assessed that is not a carrier and the other gene was unable to be assessed"; **that a "carrier at worst" embryo would be suitable for implantation after discussion with the couple**; and that the only indication of ADO in Dr. Hughes' PGD evaluation was with respect to embryo 2. (Exhibit D, p. 50-52, 64, emphasis added.)
- 59. The record also establishes that, while the specifics of the conversation about the implantation of "carrier at worst" embryos were not recorded, both plaintiffs and Dr. Licciardi confirmed in their respective depositions that the conversation took place; that it was based on the evaluation of the embryos' genetic suitability provided by Dr. Hughes' PGD report; and that the decision was made, because the "carrier at worst" embryos were the same as the parents.
- 60. Given the testimony of the plaintiffs and Dr. Licciardi about the consultation on and the acceptability to the parents to implant a "carrier at worst" embryo; given the "obvious"

meaning of Dr. Hughes' evaluation of an embryo as a "carrier at worst"; and given that Dr. Hughes' PGD analytical report mentioned ADO only with respect to embryo 2, the record conclusively refutes: Dr. Cutting's opinion that Dr. Licciardi "did not understand the results of the genetic testing results transmitted by Genesis Genetics"; Dr. Cutting's criticism that "[t]here is also no documentation of what was said during the counseling session between Dr. Licciardi and the Grossbaum's [sic] regarding the risks of potential sources of error"; and Dr. Cutting's net opinion that "Dr. Licciardi failed to adequately appraise the Grossbaums of the potential risks of using alternative embryos for transfer." (Exhibit K, p. 1.)

- 61. Dr. Cutting's criticisms of Dr. Licciardi are not shared by any other expert in this case, including plaintiffs' other liability expert, Dr. Strom, and also notably Dr. Hughes and Genesis' other expert Dr. Xu, whose interests would be expected to naturally tend to exonerate Genesis and Dr. Hughes by shifting responsibility to Dr. Licciardi.
- 62. Dr. Cutting's opinion against Dr. Licciardi is also strained. Dr. Cutting can only criticize Dr. Licciardi by treating him as if he were a geneticist, rather than as the distinctly different specialist that he is: an IVF practioner who was and is board-certified in obstetrics and gynecology and in reproductive endocrinology.
- 63. Dr. Cutting can only express opinions against Dr. Licciardi by disregarding critical facts, including the "obvious" interpretation of Dr. Hughes' PGD analysis as indicating the genetic suitability of the "maternally affected" embryo #8 as well as the "carrier at best" embryo #7, both of which were genetically equivalent to the plaintiffs, and reasonably so understood by Dr. Licciardi and by the plaintiffs based on Dr. Hughes' evaluation.
- 64. On the record of this case, Dr. Cutting's theory against Dr. Licciardi is also inconsistent with Dr. Cutting's primary opinion that the birth of plaintiffs' CF-affected child

resulted from a misdiagnosis by Genesis and Dr. Hughes which stemmed from their failure to detect an ADO because they did not use markers in their PGD tests. Dr. Cutting recognized, as did Dr. Licciardi and the plaintiffs, that CF was a recessive disorder that would not occur unless both parental genes were affected, and that the "obvious" message from Dr. Hughes' PGD evaluation report was that both embryos 7 and 8 were CF-carriers, but not CF-affected. The only acceptable conclusion is that the birth of plaintiffs' CF-affected child stemmed from the inherent risk of mis-diagnosis in PGD testing (which was always known by the plaintiffs to be a potential result), rather than from a lack of understanding by Dr. Licciardi of the evaluation actually conveyed by Dr. Hughes' PGD report, that embryos 7 and 8 were genetically suitable for implantation.

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